

# Exhibit 119

**Prinston Pharmaceutical Inc Issues Voluntary Nationwide Recall of Valsartan and Valsartan HCTZ Tablets Due to detection of a Trace Amount of Unexpected Impurity, N-nitrosodimethylamine (NDMA) in the Products**

**Contact**

**Solco Customer Service at 1-866-931-9829, Option 5**

**or email or fax to: [customerservice@solcohealthcare.com](mailto:customerservice@solcohealthcare.com); 1-866-931-0709, for Product Return**

**Press Release – Valsartan and Valsartan HCTZ Tablets Recall**

FOR IMMEDIATE RELEASE - CRANBURY, NEW JERSEY, July 13, 2018 -- Princeton Pharmaceutical Inc. dba Solco Healthcare LLC. is recalling all lots of Valsartan Tablets, 40 mg, 80mg, 160mg, and 320mg; and Valsartan-Hydrochlorothiazide Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg to the retail level. This product recall is due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), made by the manufacturer – Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

The products are indicated for the treatment of hypertension.

*The exposure to the impurity N-nitrosodimethylamine (NDMA) that was detected in valsartan product line presents an unacceptable carcinogenic risk to the intended patient population. To date, **Prinston Pharmaceutical Inc.** has not received any reports of adverse events related to this recall.*

Product	NDC Code	Lot Number	Expiry Dates	Distribution Date
VALSARTAN TABLETS 40MG 30CT	43547-367-03	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN TABLETS 80MG 90CT	43547-368-09	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN TABLETS 160MG 90CT	43547-369-09	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN TABLETS 320MG 90CT	43547-3670-09	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN/HCTZ 80MG/12.5MG 90CT TABLETS	43547-311-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 160MG/12.5MG 90CT TABLETS	43547-312-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 160MG/25MG 90CT TABLETS	43547-313-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 320MG/12.5MG 90CT TABLETS	43547-314-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 320MG/25MG 90CT TABLETS	43547-315-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018

**Hai Wang**

**129**

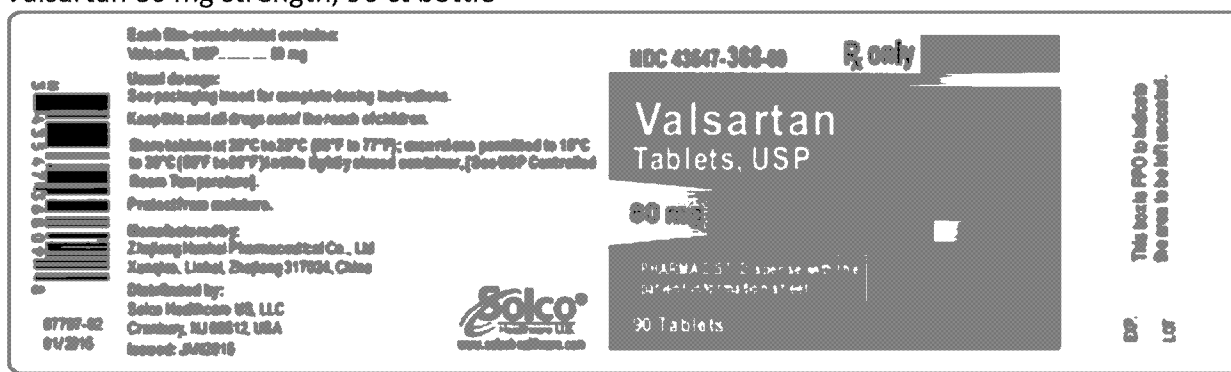
3/10/2121

The lot number and expiry date information can be found on the manufacturer's unit (see photographs below of packaged product bottle labels).

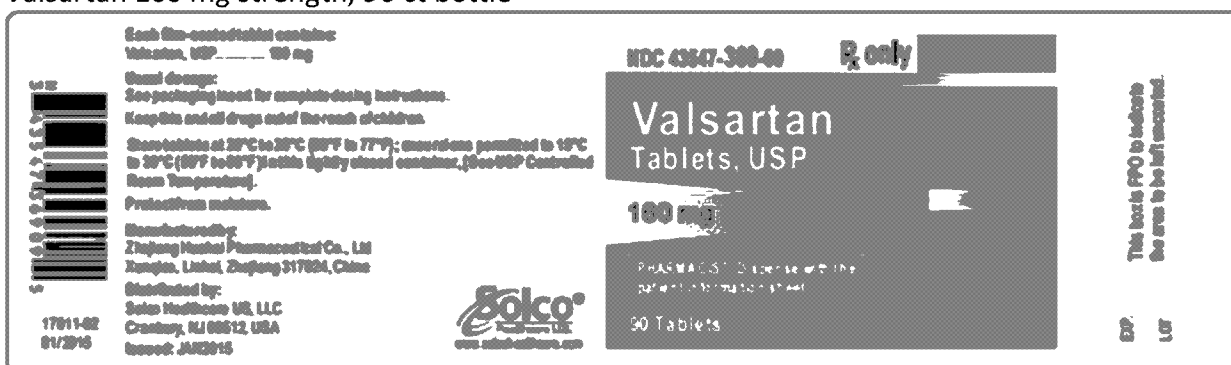
Valsartan 40 mg strength, 30 ct bottle



Valsartan 80 mg strength, 90 ct bottle



Valsartan 160 mg strength, 90 ct bottle



Valsartan 320 mg strength, 90 ct bottle

Each film-coated tablet contains:  
Valsartan, USP ..... 320 mg

**Usual dosage:**  
See packaging insert for complete dosing instructions.

Keep this and all drugs out of the reach of children.

Store tablets at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) in this tightly closed container. (See USP Controlled Room Temperature.)

Protect from moisture.

Manufactured by:  
Zhejiang Hualai Pharmaceutical Co., Ltd  
Hangzhou, Lishui, Zhejiang 317824, China

Distributed by:  
Solco Healthcare US, LLC  
Cranbury, NJ 08512, USA  
Issued: JAN2015

**Solco<sup>®</sup>**  
Healthcare US, LLC  
www.solcohealthcare.com

NDC 43547-370-00 **Rx only**

**Valsartan  
Tablets, USP**

**320 mg**

PHARMACIST Dispense with the  
patient information sheet

90 Tablets

This box is FPO to indicate  
the area to be left uncoated.

EXP. LOT

## Valsartan HCTZ 80 mg/12.5mg strength, 90 ct bottle

Each tablet contains:  
80 mg of Valsartan USP and 12.5 mg of Hydrochlorothiazide USP

**Usual dosage:** See package insert.

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) (See USP Controlled Room Temperature). Protect from moisture.

Dispense in light container (USP).

Keep this and all drugs out of the reach of children.

Manufactured by:  
Zhejiang Hualai Pharmaceutical Co., Ltd  
Hangzhou, Lishui, Zhejiang 317824, China

Distributed by:  
Solco Healthcare US, LLC  
Cranbury, NJ 08512, USA  
Issued: MAR2016

**Solco<sup>®</sup>**  
Healthcare US, LLC  
www.solcohealthcare.com

NDC 43547-311-00 **Rx only**

**Valsartan and Hydrochlorothiazide  
Tablets, USP**

**80 mg/12.5 mg**

90 Tablets

EXP. LOT

## Valsartan HCTZ 160 mg/12.5mg strength, 90 ct bottle

Each tablet contains:  
160 mg of Valsartan USP and 12.5 mg of Hydrochlorothiazide USP

**Usual dosage:** See package insert.

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) (See USP Controlled Room Temperature). Protect from moisture.

Dispense in light container (USP).

Keep this and all drugs out of the reach of children.

Manufactured by:  
Zhejiang Hualai Pharmaceutical Co., Ltd  
Hangzhou, Lishui, Zhejiang 317824, China

Distributed by:  
Solco Healthcare US, LLC  
Cranbury, NJ 08512, USA  
Issued: MAR2016

**Solco<sup>®</sup>**  
Healthcare US, LLC  
www.solcohealthcare.com

NDC 43547-312-00 **Rx only**

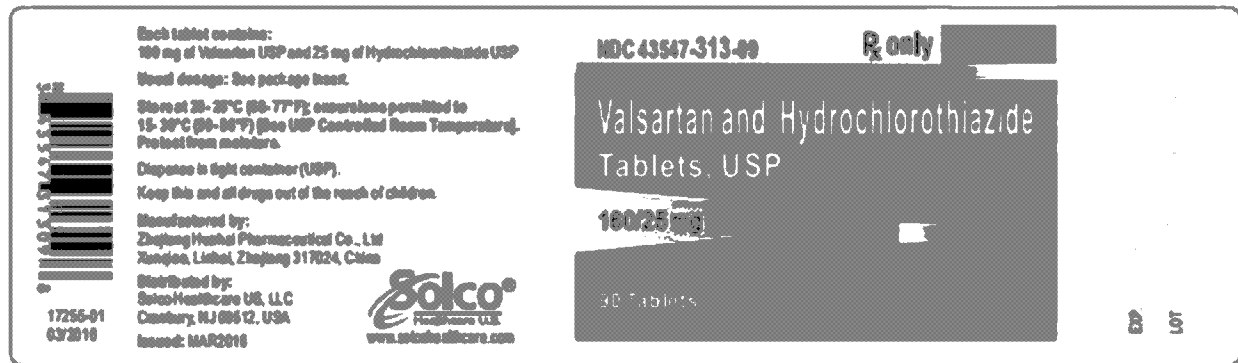
**Valsartan and Hydrochlorothiazide  
Tablets, USP**

**160 mg/12.5 mg**

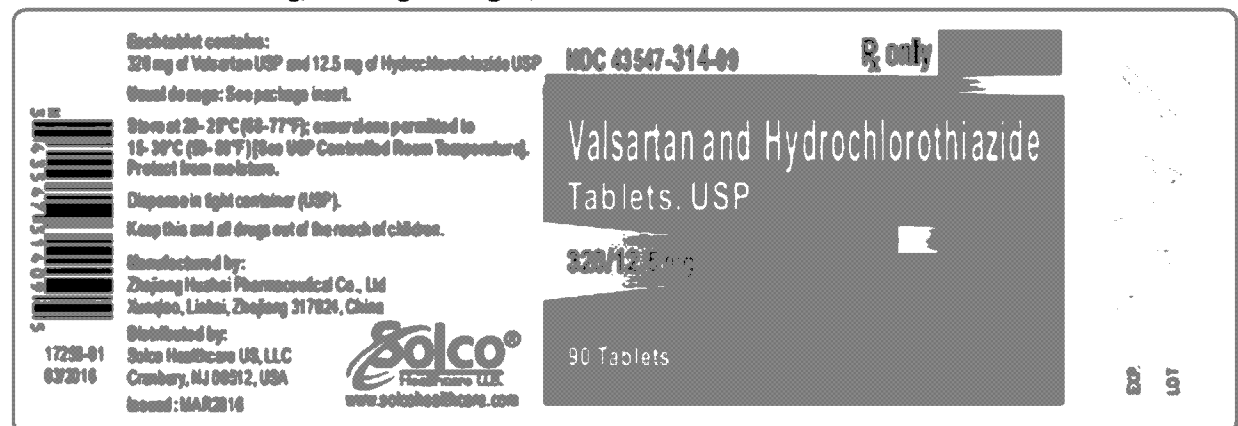
90 Tablets

EXP. LOT

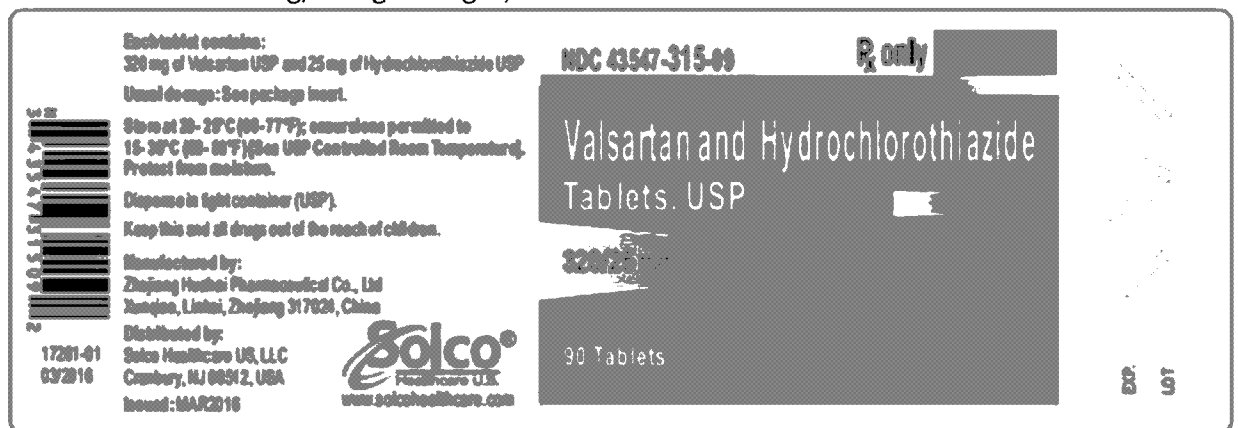
## Valsartan HCTZ 160 mg/25mg strength, 90 ct bottle



Valsartan HCTZ 320 mg/12.5mg strength, 90 ct bottle



Valsartan HCTZ 320 mg/25mg strength, 90 ct bottle



Retail pharmacies in possession of any unused products: Valsartan Tablets, 40 mg, 80mg, 160mg, and 320mg; and Valsartan-HCTZ Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg, within expiry dates from Jul 2018 to Jan 2020 should immediately return the product by following the instructions below:

- ***Pharmacists and wholesalers are asked to check their inventories, segregate any impacted inventory.***
- ***Please contact Solco Customer Service at 1-866-931-9829, Option 5, Monday through Friday (9am to 5pm EST) or email or fax to: customerservice@solcohealthcare.com; 1-866-931-0709, for the Product Return.***
- ***A call tag, a pre-printed, pre-paid return label will be provided to you for product return; return is free of charge.***
- ***Return products to:***

DLSS (Dohmen Life Science Services)

Attn: Returns Department

4580 S. Mendenhall, Memphis, TN 38141

Solco is notifying its distributors and customers by letter and email and is arranging for return of all recalled products. Pharmacies and wholesalers that received the impacted products will receive a letter as well as a copy of this press release with their recall notification information.

If you have any questions regarding this recall, please call 1-866-931-9829, Option 5, between the hours of 9:00 a.m. to 5:00 p.m. EST Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product. Additional information regarding this recall affected products' lots and expiry dates can be found

at <http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffectedLots.pdf> or to download at <http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffectedLots.xlsx>

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).